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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/805,337	03/13/2001	Brendan F. Murphy	DI-5585L (BXTD 9000.1)	1925

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EXAMINER

CHISM, BILLY D

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 08/26/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/805,337

Applicant(s)

MURPHY, BRENDAN F.

Examiner

B. Dell Chism

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 3-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6 & 11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This Office Action is in response to Paper No. 13, filed 28 May 2003, wherein Applicant elected with traverse the Group I, claims 1-2. Claims 3-30 are withdrawn from consideration as nonelected subject matter.

Applicant argues that restriction was improper since the examiner failed to establish independence or distinction between the Groups I-VI. The Examiner indicated in the restriction that one of the reasons for restriction, aside from the established independence or distinction between all groups, was that the search for any one group was not required for any other one group. Thus, a comprehensive search of one group would not be inclusive of all possible search strategies for any other one group, thus, making a search for more than any one elected group burdensome on the Examiner. For these reasons and the reasons in the previous office action, the Applicant's arguments are not found persuasive and the restriction is made FINAL.

### ***Claim Rejections - 35 USC § 101***

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 1-2 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

The specification does not disclose any specific and substantial asserted utility or well-established utility for the FHR-5 or fragments thereof, or for sequences with at least 90% sequence identity to the claimed sequence. The specification states that the FHR-5 is unique in the FH family and that it co-localizes with the C5b-9 complexes, thus, the FHR-5 can be used as

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a marker (page 9 lines 14-23). However, there is no asserted utility for the disclosed complexes, nor is there a specific and substantial asserted or well-established utility for the FHR-5 protein. Furthermore, the specification gives a prophetic function of the FHR-5 protein by stating, "It can be found associated with mature complement C5b-9 complex, and is believed to play a role in the complement cascade (page 9 line 3-5)." Thus, Applicant has not provided a specific and substantial asserted or well-established utility for the claimed FHR-5 sequence or fragments thereof.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-2 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-2 are directed in part to an amino acid sequence comprising at least 90% sequence identity with SEQ ID NO: 2 (claim 1), and a fragment of SEQ ID NO: 2 (claim 2), disclosed in the specification, and concepts regarding the meaning of "percent" (%) (page 7, lines 21-30); however, there is no description of the differences brought about by a percent identity difference (e.g. if there is a identity difference of 92, 94 or 96%) that would result in a

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biologically active protein. Applicant may wish to amend these claims to delete the percents, and indicate a specific, measurable function. There is no apparent discussion of what part(s) of the protein would have to remain, and since there are no discussions regarding the actual function of the protein, fragments thereof or sequences with at least 90% identity to SEQ ID NO: 2, then there is no way of knowing which portions or fragments of the compound would have to remain for a proper function.

5. Claims 1-2 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is an enablement rejection.

Claims 1-2 are rejected, specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. The specification does not provide a specific and substantial asserted utility or a well-established utility for a “substantially purified factor H-related protein 5, comprising a primary amino acid sequence selected from the group consisting of” SEQ ID NO: 2, or a sequence with at least 90% sequence identity to SEQ ID NO: 2, or a fragment of SEQ ID NO: 2. Thus, one skilled in the art would not know how to make and/or use the claimed invention.

Claim 1 is also rejected under 35 U.S.C. 112, first paragraph wherein the claim is not enabled for “an amino acid sequence having at least 90% sequence identity to SEQ ID NO: 2.”

Sequence homology, alone, cannot be accepted in the absence of supporting evidence, because the relevant literature acknowledges that function cannot be predicted based solely on structural similarity to a protein found in the sequence databases. In the present case, the specification does not disclose any sequence(s) that would be representative of sequences having at least 90% sequence identity, nor is there disclosure regarding the function of sequences having at least 90% sequence identity to SEQ ID NO: 2..

For example, Skolnick et al. (Trends in Biotech. 18:34-39, 2000) state that knowing the protein structure by itself is insufficient to annotate a number of functional classes, and is also insufficient for annotating the specific details of protein function (see Box 2, p. 36). Similarly, Bork (Genome Research 10:398-400, 2000) states that the error rate of functional annotations in the sequence database is considerable, making it even more difficult to infer correct function from a structural comparison of a new sequence with a sequence database (see especially p. 399). Such concerns are also echoed by Doerks et al. (Trends in Genetics 14:248-250, 1998) who state that (1) functional information is only partially annotated in the database, ignoring multi functionality, resulting in under-predictions of functionality of a new protein and (2) over-predictions of functionality occur because structural similarity often does not necessarily coincide with functional similarity. Smith et al. (Nature Biotechnology 15:1222-1223, 1997) remark that there are numerous cases in which proteins having very different functions share structural similarity due to evolution from a common ancestral gene.

Brenner (Trends in Genetics 15:132-133, 1999) argues that accurate inference of function from homology must be a difficult problem since, assuming there are only about 1000 major gene superfamilies in nature; most homologs must have different molecular and cellular

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functions. Finally, Bork et al. (Trends in Genetics 12:425-427, 1996) add that the software robots that assign functions to new proteins often assign a function to a whole new protein based on structural similarity of a small domain of the new protein to a small domain of a known protein. Such questionable interpretations are written into the sequence database and are then considered facts. Therefore, based on the art's recognition that one cannot rely upon structural similarity alone to determine functionality, the specification fails to teach the skilled artisan the utility of the claimed protein of SEQ ID NO: 2, which has no known function described in the specification. Thus, the present application is not enabled for "an amino acid sequence having at least 90% sequence identity to SEQID NO: 2."

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected for the indefinite recitation of the phrase, "an amino acid sequence having at least 90% sequence identity to SEQ ID NO: 2." It is unclear which portions or residues or series of residues are to compose the 90% identity to SEQ ID NO: 2. Claim 1 also requires the insertion of "and" or "or" between Markush items a) and b) in order to be in proper form.

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Claim 2 is rejected for the indefinite recitation of the phrase, "fragment of SEQ ID NO: 2", wherein it is unclear what comprises a fragment, i.e., are all fragments of SEQ ID NO: 2 comprised.

### *Conclusions*

No claims are allowed.

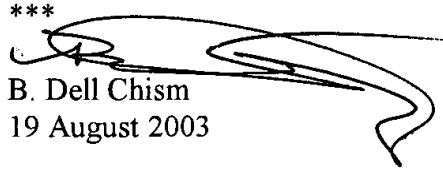
Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism whose telephone number is 703-306-5815. The examiner can normally be reached on 7:30 AM - 4:30 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 703-306-3220. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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B. Dell Chism  
19 August 2003



CHRISTOPHER R. TATE  
PRIMARY EXAMINER